No. 05-35264

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RANCHERS CATTLEMAN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,
Plaintiff-Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,
Animal and Plant Health Inspection Service, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Montana

MOTION OF *AMICUS CURIAE* TYSON FOODS, INC. FOR LEAVE TO FILE REPLACEMENT BRIEF IN SUPPORT OF APPELLANTS AND REVERSAL OF THE DISTRICT COURT'S PRELIMINARY INJUNCTION ORDER

Amicus curiae Tyson Foods, Inc. ("Tyson") respectfully moves this Court for an order granting Tyson leave to file a replacement brief in place of the *amicus curiae* brief Tyson timely filed with this Court in the above captioned matter. In support of this motion, Tyson states as follows:

1. The above captioned matter involves a review of a preliminary injunction order entered by the district court in Montana halting the

implementation of a regulation concerning, *inter alia*, the importation of Canadian cattle under 30 months of age into the United States for slaughter. The expedited briefing schedule set by this Court in this appeal required the appellant, the United States Department of Agriculture, to file its initial brief on April 14, 2005. The United States Department of Agriculture timely filed its brief on April 14, 2005.

2. Tyson contacted the parties to the appeal and requested their permission to file an *amicus curiae* brief in support of the United States Department of Agriculture. All parties to the proceedings consented to Tyson filing an *amicus curiae* brief. Pursuant to Fed. R. App. P. 29(e), Tyson's *amicus curiae* brief was due to be filed on April 21, 2005.

3. Tyson timely filed an *amicus curiae* brief on April 21, 2005 by sending an original plus 15 copies via Federal Express overnight delivery to the Clerk of the Court, and by serving (in the same manner) two copies on the parties to the proceedings. Tyson's *amicus curiae* brief was received by the clerk on April 22, 2005 and noted as filed on the docket sheet.

4. During a review of the brief subsequent to its filing, it has come to the attention of attorneys for Tyson that certain final proofreading and citecheck changes were not incorporated into the version of the brief that was filed and served. All of these changes are non-substantive. They are either (a) minor proofreading edits necessary to correct typos, such as misspellings or stray words

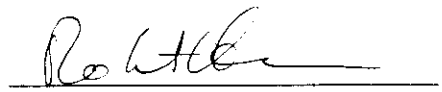
that were intended to be deleted but were not, (b) edits necessary for consistency of treatment of abbreviations, or (c) edits necessary for correction of or consistency in the form of citations, especially citations to items available over the internet.

5. Tyson has now incorporated those edits into the attached proposed "Replacement Brief of *Amicus Curiae* Tyson Foods, Inc. In Support Of Appellants And Reversal Of The District Court's Preliminary Injunction Order." (Attached as Exhibit A.) As noted above, the attached Replacement Brief makes no substantive change to the brief that was timely filed. Tyson is submitting, along with this motion, the requisite number of copies for filing: an original of the Replacement Brief, plus 15 copies.

6. Tyson is also simultaneously serving upon each of the parties listed in the attached service list two copies of the Replacement Brief.

WHEREFORE, *amicus curiae* Tyson Foods, Inc. respectfully requests that this Court enter an order granting Tyson leave to file a Replacement Brief in the above captioned matter.

Respectfully submitted,



Carter G. Phillips
Alan Charles Raul
Mark D. Hopson
Jay T. Jorgensen
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Robert N. Hochman
Chad W. Pekron
SIDLEY AUSTIN BROWN & WOOD LLP
Bank One Plaza
10 South Dearborn Street
Chicago, IL 60603
(312) 853-7000

CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2005 I caused one copy of the foregoing Motion of *Amicus Curiae* Tyson Foods, Inc. for Leave to File Replacement Brief In Support of Appellants and Reversal of the District Court's Preliminary Injunction Order to be served by Federal Express overnight delivery on the following:

A. Clifford Edwards
Edwards, Frickle, Anne-Hughes,
Cook & Culver
1601 Lewis Avenue, Suite 206
Billings, MT 59104

Russell S. Frye
Frye Law PLLC
3050 K Street, NW
Suite 400
Washington, D.C. 20007-5108

William L. Miller
The William Miller Group, PLLC
3050 K Street, NW, Fourth Floor
Washington, D.C. 20007

Philip C. Olsson
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, NW
Washington, D.C. 20036-2220

Mark B. Stern
Michael S. Raab
Civil Division, Room 7256
Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530-0001

I also hereby certify that on April 26, 2005 I filed an original and 4 copies of the foregoing Motion of *Amicus Curiae* Tyson Foods, Inc. for Leave to File Replacement Brief In Support of Appellants and Reversal of the District Court's Preliminary Injunction Order by causing them to be sent by Federal Express overnight delivery to:

Ms. Cathy Catterson
Clerk, United States Court of Appeals for the Ninth Circuit
95 Seventh Street
San Francisco, CA 94103-1526

Robert N. Hochman

EXHIBIT A

No. 05-35264

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REPLACEMENT BRIEF OF *AMICUS CURIAE* TYSON FOODS, INC. IN SUPPORT OF APPELLANTS AND REVERSAL OF THE DISTRICT COURT'S PRELIMINARY INJUNCTION ORDER

Robert N. Hochman
Chad W. Pekron
SIDLEY AUSTIN BROWN & WOOD LLP
Bank One Plaza
10 South Dearborn Street
Chicago, IL 60603
(312) 853-7000

Carter G. Phillips
Alan Charles Raul
Mark D. Hopson
Jay T. Jorgensen
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Attorneys for Tyson Foods, Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 *amicus* Tyson Foods Inc. states that it has no parent corporation and no publicly held corporation owns 10% or more of its stock.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES

STATUTES AND REGULATIONS

SCHOLARLY AUTHORITIES

OTHER AUTHORITIES

INTEREST OF *AMICUS*

Amicus Tyson Foods, Inc. is the world's largest processor and marketer of chicken, beef, and pork. Tyson is also the nation's largest beef packer, with 10 plants in 7 states. Tyson is 100% dedicated to food safety. Food safety is not only a crucial social and legal responsibility, it is good business—the public will not purchase meat when people lack confidence that the meat they buy is safe to consume. Given Tyson's role in the marketplace, no private party could be more committed to the continued availability of an adequate supply of wholesome, healthy cattle, the preservation and promotion of food safety, the confidence of the consuming public in the food supply, and adherence to sound scientific principles by the regulators in our country and those of our trading partners.

Tyson voluntarily has undertaken and promoted safe food practices beyond those required by law or regulation, including slaughtering cattle that typically are less than 24 months old, and hence outside the BSE risk group. Tyson also began removing specified risk materials ("SRMs") before any regulations required it to do so. Tyson spends tens of millions of dollars each year on food safety and quality assurance, and is committed to promoting government regulations that are consistent with its goals of securing a safe and wholesome food supply and promoting consumer confidence in the safety of beef in the United States. Tyson therefore is submitting this brief in support of the United States

Department of Agriculture ("USDA"), confident that the final rule under review embodies a rational, cautious and crucial component of the United States's overall regulatory program to prevent BSE from threatening our nation.[1]

ARGUMENT

To obtain a preliminary injunction, R-CALF was required to prove "'either: (1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in [their] favor.'" *United States v. Schiff*, 379 F.3d 621, 625 (9th Cir. 2004) (alteration in original) (quoting *Southwest Voter Registration Educ. Project v. Shelley*, 344 F.3d 914, 917 (9th Cir. 2003) (en banc) (per curiam)). In addition, "[t]he district court must ... consider whether the public interest favors issuance of the injunction." *Shelley*, 344 F.3d at 917. The less confident a court is that plaintiff's claim will succeed on the merits, the more confident it must be that that "the public interest and balance of hardships tip in [its] favor." *Id.* at 918.

This Court reviews a district court's decision to grant a preliminary injunction for an abuse of discretion. *Schiff*, 379 F.3d at 625. A district court abuses its discretion when its decision is based on either an erroneous legal standard or on clearly erroneous factual findings. *United States v. Estate Pres. Servs.*, 202 F.3d 1093, 1097 (9th Cir. 2000). As demonstrated below, the district

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[1] All parties to this litigation have consented to the filing of this *amicus* brief.

court abused its discretion both by applying an erroneous legal standard to its review of agency decisions and by making clearly erroneous factual findings with respect to the systems in place, both in the United States and Canada, to protect Americans and American cattle from the threat of BSE infection.

First, with respect to R-CALF's likelihood of success on the merits, the district court's order failed to analyze the disputed rule in accordance with the correct legal and regulatory standards. The court failed to cite, and failed to apply, the relevant statutory language applicable to the Animal and Plant Health Inspection Service ("APHIS") rule in question. Instead, the court merely invoked broad "health and welfare" recitals in the congressional "findings" section of the statute to justify its holding that the agency's rule was likely to be found arbitrary and capricious in violation of the Administrative Procedure Act. By so doing, the court glossed over the actual mandate of APHIS—which is to protect animal health—and ignored the comprehensive and well coordinated regulatory regime, of which the challenged APHIS rule is but one part.

In fact, the federal government, including but not limited to APHIS, has designed and executed an elaborate regulatory scheme to protect food safety and the American food supply against the risk of BSE. The opinion below failed to distinguish between the statutory obligations of APHIS, the Food Safety and Inspection Service ("FSIS") and the Food and Drug Administration ("FDA"), and

therefore improperly discounted the elaborate regulatory precautions that the U.S. government has imposed throughout the food chain.[2]

The final rule under review emerged from APHIS. The district court treated APHIS, which implements the *Animal* Health Protection Act, as if it were primarily responsible for "the health and welfare of the *people* of the United States." (Order at 8 (emphasis added).) This is misleadingly incomplete. As its name suggests APHIS is, as relevant here, primarily responsible for *animal* safety. APHIS's regulations surely *impact* food safety, because the safety of our animal population affects the safety of our food supply. But other arms of the government, including FSIS and the FDA, are primarily responsible for ensuring food safety, which, together with APHIS's animal health safety rules, promotes the "health and welfare of the people of the United States."

Under the prevailing standards of judicial review under the APA, the district court was obligated both to grant deference to the agency's regulatory expertise *and* to engage in probing review of the administrative record to ensure

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[2] *See generally* http://www.aphis.usda.gov/lpa/issues/bse/bse.html (last visited April 19, 2005) (APHIS website devoted to latest action and information regarding BSE protections); http://www.fsis.usda.gov/Fact_Sheets/Bovine_Spongiform_Encephalopathy_BSE/index.asp (last visited April 19, 2005) (same for FSIS); http://www.fda.gov/oc/opacom/hottopics/bse.html (last visited April 19, 2005) (same for FDA).

that the agency exercised its regulatory responsibilities in a rational manner. The district court did neither.

In fact, the court barely acknowledges that R-CALF is seeking to halt the implementation of a final rule adopted in 2005 after years of careful study and analysis by an agency acting within its area of expertise. The district court simply failed to engage the administrative record in this case, as it is obligated to do when reviewing agency action. "Where scientific and technical expertise is necessarily involved in agency decision-making, especially in the context of prediction ... the Supreme Court has held that a reviewing court must be highly deferential to the judgment of the agency." *National Wildlife Fed'n v. U.S. Army Corps of Eng'rs*, 383 F.3d 1163, 1174 (9th Cir. 2004). Although the federal courts can and should play a significant role in reviewing agency decisions with care, a reviewing court must engage the factual record compiled by the agency with appropriate respect for the agency's expertise and fact-finding.

Here, the district court uncritically adopted the faulty factual claims of R-CALF, and simply ignored the substantial and compelling evidence of the extraordinary level of intra- and inter-governmental coordination with respect to BSE. The record USDA compiled after years of study and analysis of the BSE issue so strongly supports the final rule under review that it could easily survive

review even without the benefit of the deference that courts owe, but this district court did not accord, agency findings.

In addition to essentially ignoring the detailed administrative record, the district court misapplied an important administrative law principle. The district court treated the agency's 2003 emergency rule as if it held the legal status of a well reasoned and longstanding policy. It does not. That rule was adopted in response to the discovery of a single cow of Canadian origin diagnosed with BSE. Yet the district court erroneously treated that rule as presumptively correct and, in fact, permanent. In fact, the rule was adopted for the purpose of allowing time for the careful study that the agency subsequently undertook. Agencies need flexibility in emergency circumstances to act quickly in the public interest, confident that they are not locking themselves into decisions made *without* the luxury of time to conduct more deliberate scientific review and analysis.

Indeed, upholding the district court's order would create a perverse incentive for agencies to avoid taking quick, emergency action to deal with fast-breaking, but poorly characterized, circumstances. The district court's ruling would tend to shackle agencies with standards they might not be able to justify as a longer term response.

Finally, the district court improperly analyzed the public interests at stake in this case. USDA has ably ensured that reopening the border to Canadian

cattle will not threaten American cattle or American consumers. The district court erroneously equated R-CALF's view of the threat—which is influenced by its own trade protectionist policies and financial interests—with the broader public interest. The decision below, however, interferes with the United States's regulatory and trade relationship with Canada, a relationship that fostered extraordinary cross-border cooperation between the two countries to ensure that the cattle supplies of both countries remain safe. Such efforts merit greater respect than that provided by the district court. More broadly, the decision takes an approach to the BSE issue that will only bolster the anti-American views of other nations. European nations and Japan have seized on insignificant evidence of BSE infections to justify closing their borders to American beef. This decision does the same, and inadvertently provides a patina of credibility to other nations' protectionist impulses.

The overall result of the district court's approach is higher domestic beef prices for consumers and greater friction with our trading partners, all with no corresponding public health benefits. In short, the district court's approach is bad food safety policy, bad administrative law, and bad for consumers. It is good only for certain domestic ranchers who promote protectionism out of mistaken self-interest. The decision below should be reversed and the final rule should be permitted to take effect pending a final ruling of the district court.

I. R-CALF CANNOT SUCCEED ON THE MERITS.

In considering the likelihood of success of R-CALF's claim on the merits, the district court abused its discretion by applying an erroneous legal standard to the agency's action, and by making clearly erroneous findings because the court failed to confront the extensive factual record compiled by the agency. The order granting R-CALF's application for a preliminary injunction should be reversed.

A. The District Court Failed To Confront The Detailed Factual Record The Agency Compiled Which Supports The Final Rule.

The district court's preliminary injunction ruling bears little resemblance to standard judicial review of agency action. To be sure, the district court recites certain aspects of the appropriate standard of review. "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." (Order at 7.) And the court noted that its obligation was to "carefully review the record to 'ensure that agency decisions are founded on a reasoned evaluation of the relevant factors.'" (*Id.* (quoting *Arizona Cattle Growers' Ass'n v. United States Fish & Wildlife*, 273 F.3d 1229, 1236 (9th Cir. 2001)). However, what the district court said and what the district court did are two very different things.

Nothing in the district court's order provides reason to believe that the court "carefully review[ed] the record." *Arizona Cattle Growers*, 273 F.3d at

1236. Even a casual comparison of the district court opinion with R-CALF's memorandum in support of its motion for a preliminary injunction reveals that the district court simply accepted wholesale R-CALF's presentation and analysis of the facts. And the administrative record available to the court demonstrates how faulty R-CALF's presentation and analysis were. Following R-CALF's lead, the district court ignored the elaborate intra- and inter-governmental regulatory structure in place to combat the BSE threat. Indeed, the administrative record at hand incorporates the best scientific information available to the agency; it could have easily withstood the most searching review, let alone the cursory one conducted by the district court.

Amicus does not seek court "rubber-stamp[ing]" of agency decisions. *Federal Labor Relations Auth. v. Aberdeen Proving Ground*, 485 U.S. 409, 414 (1988) (per curiam); *NLRB v. Brown*, 380 U.S. 278, 291-92 (1965). Rather, *amicus* submits that the district court was obligated to undertake "an inquiry into the facts [of an agency decision that is] searching and careful," *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977), and to ensure that the agency's decisionmaking process was orderly, scientifically valid and reliable. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983) (requiring agency to "cogently explain why it has exercised its discretion in

a given manner"); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167 (1962) (requiring "findings" and "analysis" to justify why agency "exercised its expert discretion" as it has). The court below did not engage in such an inquiring judicial review.

Of course, proper judicial review is limited; a court must defer to agency expertise, and thus accept an agency's judgment regarding the adequacy of its own experts' analyses, even if the court might have rejected the analysis in the absence of a deferential standard of review. *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989). Given the district court's failure both to inquire and to defer, *this* Court should now perform a careful review of the record before the agency. *Virginia Agric. Growers Ass'n v. Donovan*, 774 F.2d 89, 92-93 (4th Cir. 1985) (district court decision holding agency rule arbitrary and capricious based upon testimony of plaintiff's experts reversed in favor of court of appeals' review of record before agency which fully supported rule). Such review will provide a compelling basis to uphold the agency's decision, and will actually demonstrate that the actions of the U.S. government to combat the threat of BSE from Canadian imports in the United States have been very far from arbitrary and capricious.

1. The District Court Failed To Grasp That The Final Rule Is The Product Of A Highly Professional And Impressive Exercise In Intra- and Inter-Governmental Regulatory Assessment And Coordination.

The only provisions of the Animal Protection Act that the district court found APHIS likely to have violated are the Act's broad recitals regarding the need to "protect the health and welfare of the people of the United States." (Order at 8 (citing 7 U.S.C. § 8301(1)(B) & (5)(B)(iii)).) The provisions cited by the district court, however, are not statutory directives at all. Rather, they are congressional *findings* that protection of animals from disease will protect human health and welfare, and that effective regulations designed to promote protection of animals from disease will do the same. These recitals are not a *mandate* for APHIS to single-handedly assume responsibility for human health. But, other than this "violation" of the recital language, the district court neither invoked nor applied any of the substantive provisions of APHIS's organic statute. This alone was serious judicial error. *Southern Utah Wilderness Alliance v. Dabney*, 222 F.3d 819, 825-26 (10th Cir. 2000) (district court review of agency action must proceed in light of proper understanding of enabling legislation); *Black Citizens for a Fair Media v. FCC*, 719 F.2d 407, 411 (D.C. Cir. 1983) (courts determine agency's mandate by consulting relevant act, giving due deference to agency's interpretation of its own act).

Under its organic statute, APHIS must protect *animal* health, as *part* of the government's overall efforts to protect the integrity of the food supply and, ultimately, human health. *See* 7 U.S.C. § 8303(a)(1) (authorizing action to "prevent the introduction into or dissemination within the United States of any pest or disease of livestock").[3] This is not a minor issue. There is a great difference between treating APHIS as the sole guardian of America's food supply (as the district court did) and understanding APHIS's role in protecting animal health, which is but one part of a comprehensive and multi-faceted government effort to ensure the safety of the food supply. Because the regulatory obligation to protect health and welfare is the collective mission of a variety of agencies, the government effort to combat BSE wisely relies upon the coordinated contributions of agencies with complementary areas of expertise.

APHIS, as noted above, properly understands its mission to protect animal health. *See* USDA Br. at 5 (noting that APHIS "is the agency ... that guards against the introduction of various animal diseases to the United States").[4] *FSIS* is charged with ensuring that the United States's supply of meat products is

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[3] *See* Animal & Plant Health Inspection Serv., U.S. Dep't of Agric., About APHIS, at http://www.aphis.usda.gov/lpa/about/welcome.html (last visited April 19, 2005) ("Without APHIS protecting America's animal and plant resources from agricultural pests and diseases, threats to our food supply and to our Nation's economy would be enormous.").

[4] This Court should defer to the agency's own understanding of its mandate. *Sierra Club-Black Hills Group v. United States Forest Serv.*, 259 F.3d 1281, 1286

safe. 61 Fed. Reg. 38806, 38807 (July 25, 1996); *see* The Federal Meat Inspection Act, 21 U.S.C. § 603(a). *FDA* protects the safety of animal feed (and non-meat foods as well as pharmaceutical products). *See* 69 Fed. Reg. 42256, 42256 (July 14, 2004) (FDA adopts rule prohibiting use of certain cattle material in animal feed to "minimize human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent").

In adopting the final rule under review, APHIS was conscious of its role within the overall government effort to combat BSE. 70 Fed. Reg. 460, 465-66 (Jan. 4, 2005) (describing roles of various agencies). Each of the agencies – APHIS, FSIS and FDA – carries out its role in addressing separate BSE risks.[5]

(10th Cir. 2001).

[5] Animal & Plant Health Inspection Serv., U.S. Dep't of Agric., *Strategic Plan 2003-2008*, at 1 (Mar. 2005), at http://www.aphis.usda.gov/lpa/about/strategic_plan/APHIS_SPlan3-05.pdf (describing APHIS as an "action-oriented agency that works with other Federal Agencies") (last visited April 19, 2005); Food Safety & Inspection Serv., U.S. Dep't of Agric., *Fulfilling the Vision: Initiatives in Protecting Public Health* 9 (July 2004), at http://www.fsis.usda.gov/PDF/Fulfilling_the_Vision.pdf (describing cooperation between APHIS and FSIS in animal surveillance and post-mortem testing) (last visited April 19, 2005); U.S. Food & Drug Admin., *Agencies Work to Corral Mad Cow Disease*, FDA Consumer Mag., May-June 2004, at http://www.fda.gov/fdac/features/2004/304_cow.html (describing coordinated response of USDA to trace origin of cow diagnosed with BSE and FDA to ensure that no portions of the cow found their way into feed products) (last visited April 19, 2005). APHIS and FSIS have "come together to lead USDA's actions in the prevention, monitoring and control of ... BSE in the U.S. livestock and food supply." (AR9532.)

In addition, the United States government has worked closely with Canadian officials in connection with both the initial investigation of the May 2003 discovery, and with ensuring that the Canadian and U.S. protection systems will effectively prevent the introduction of BSE into the U.S. cattle population. USDA has carefully examined Canada's response to the May 2003 discovery of a Canadian-origin cow infected with BSE, and it has concluded that Canada's surveillance and response procedures are strong. (AR8328-29.)[6] United States and Canadian officials continue to work cooperatively to develop standards. In March 2005, "Senior Animal Health Officials" from Mexico, Canada and the United States gathered to coordinate and standardize the measures they take to ensure against the spread of BSE in North America.[7] And cross-border cooperation extends also to ensuring adequate compliance with the high standards the nations have set.[8]

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[6] The administrative record, which was submitted to the district court, is cited (AR___). The excerpts of record compiled for this Court are cited (ER___).

[7] *Report of the North American Chief Veterinary Officers on the Harmonization of a BSE Strategy* 1 (Mar. 2005), at http://www.aphis.usda.gov/lpa/issues/bse/04-01-05na_bse_harmonization.pdf (last visited April 19, 2005).

[8] U.S. Dep't of Agric., *U.S. Department of Agriculture's Assessment of the Canadian Feed Ban* (Feb. 2005) ("*USDA Assessment*"), at http://www.aphis.usda.gov/lpa/issues/bse/CAN-FeedBanReview.pdf (describing results of USDA team's investigation of Canadian cattle industry's compliance with the Canadian feed ban and expressing confidence in effectiveness of the ban) (last visited April 19, 2005).

In sum, the level of inter-agency and inter-governmental planning and coordination in response to BSE concerns has been substantial. It is a model for well planned and coordinated action, and it readily withstands appropriate judicial review.

2. USDA Compiled An Impressive Scientific Record In Support Of Its Conclusion.

There are a number of errors in the decision below resulting from the trial court's failure to properly review the administrative record. *Amicus*, whose business depends on confidence in the safety of U.S. meat, welcomes a "searching and careful" review of the record, *Overton Park*, 401 U.S. at 416, because the final rule in question was in fact thoughtfully and effectively designed to prevent the introduction or establishment of BSE in the U.S. cattle stock.

a. APHIS Adequately Explained Its Standard For Determining That Canada Is A "Minimal Risk" Region.

The district court complains that APHIS failed to explain the standard it used to determine that importation of Canadian beef poses a minimal risk to the U.S. cattle stock. The court singled out one sentence in the final rule to support the assertion: APHIS chose not to adopt "'specific thresholds for an acceptable number of cases [of disease] in humans or animals.'" (Order at 9 (citing 70 Fed. Reg. at 473).) The sentence was made in response to a comment, and, when read in context, makes clear that APHIS does not believe there is an acceptable number of

cases. The district court simply equated the absence of numerical thresholds with the absence of any standard at all and with the tolerance of some number of BSE cases. *Id.* This is clearly erroneous.[9]

The court's imposition of this one, narrow quantitative "threshold" as the *sine qua non* of the agency's rationality is unfounded. As APHIS explained in its final rule, there is no requirement that a standard be quantitative at all. The internationally respected *Office International des Epizooties* ("OIE") specifies that "[b]oth qualitative and quantitative risk methods are valid."[10]

Indeed, in recognition of the complexity of the issue, APHIS used both qualitative standards and quantitative standards in reaching its conclusion. APHIS employed qualitative standards to define the risk that cattle imported from a particular region might contract BSE. 70 Fed. Reg. at 473 (regions evaluated based on their own import restrictions to prevent import of infected animals, animal products and animal feed, the region's surveillance of its own BSE levels, and the existence of feed ban with no evidence of significant noncompliance).

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[9] *Cf.* Raul & Dwyer, *"Regulatory* Daubert*": A Proposal to Enhance Judicial Review of Agency Science by Incorporating* Daubert *Principles into Administrative Law*, 66 Law & Contemp. Prob. 7, 38 (2003) ("By providing consistent standards for judicial review, [regulatory application of] *Daubert* compels courts to focus on the quality of the agency's science, thus protecting agency decisions from invalidation through arbitrary reliance on isolated statements in an agency rule.").

[10] OIE, *Guidelines for Risk Analysis, in Terrestrial Animal Health Code*, ch. 1.3.2, art. 1.3.2.3 (last updated June 9, 2004), at http://www.oie.int/eng/normes/mcode/en_chapitre_1.3.2.htm (last visited April 19,

Moreover, APHIS explained its reasons for not choosing quantitative standards when evaluating that risk. Rigid numerical criteria could be over-inclusive because a region with poor controls might pose an unacceptable risk even though it has had few or no confirmed cases of BSE-infected animals (especially if that region has a weak surveillance system). *Id.* Likewise such rigid criteria might be under-inclusive if a region has instituted strong control measures that substantially reduce the risk of infection. *Id.* APHIS also employed quantitative (numerical) analysis from the Harvard-Tuskegee study in analyzing the risk of BSE spreading within the United States. *Id.* at 504-05. The experts who conducted the study concluded that if even 10 infected animals entered the country, there would be a 75% to 95% chance that there would be *no* new cases of BSE at all. (AR1872-73.) In the exceedingly unlikely event that there are as many as 11 new cases, the model still predicts that there is "virtually no chance that there are any infected animals 20 years following the import of infected animals." (AR1873.)

b. The Record Refutes The District Court's Assertion That Importation Of Cattle From Canada Will Pose A "Potentially Catastrophic Risk Of Danger To Beef Consumers In The U.S."

Most fundamentally, the district court failed properly to approach the question of how to manage the risk of BSE. The district court's discussion of the

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2005).

adequacy of BSE precautions proceeds as if each step in the animal health and food safety process must, standing alone, provide 100% assurance against the transmission of the BSE-causing agent. The district court repeatedly criticizes USDA for failing to present scientific data that "dismiss[es] the possibility" that infection can be spread. (Order at 14 (discussing rendered animal fat bovine blood in feed); *id.* at 12 (discussing possibility of BSE transmission through saliva and blood); *id.* at 15 (crediting R-CALF's evidence that SRM removal does not "[e]liminate[] all [r]isks").) In contrast with the court's adoption of R-CALF's irrational approach, the agency's final rule focuses on maximum protection against the introduction or transmission of BSE agents to eliminate any threat to animal or human health.

BSE is caused by an infectious agent called "prions." An animal infected with the BSE-causing agent exhibits no symptoms until long after it has acquired some prions. (AR 1837) (median incubation period is four years); 70 Fed. Reg. at 512 ("[c]urrent testing methodology can only detect BSE, at the earliest, a few months before an animal exhibits clinical signs"). But the incubation period reduces for an animal exposed to a high dose of BSE prions. *Id.* at 483. For this reason, APHIS was confident that slaughter before 30 months of age from a region with strong BSE controls was safe. *Id.* In addition, it is widely accepted that human beings enjoy a natural advantage over cattle in resisting BSE.

This conclusion is based on the fact that in Great Britain in the mid-1980s, more than *one million* head of cattle were infected with BSE. Yet there have been only 150 cases of BSE's human counterpart, vCJD infection, *worldwide*. *Id.* at 505. "This [species] barrier suggests that it is unlikely that that there would be any measurable effects on human health from small amounts of infectivity entering the food chain." *Id.*

APHIS's final rule explains how the safety procedures in Canada, combined with the protections against the spread of infection in the United States, created a multi-layered defense against BSE. A review of even just the most important aspects of the protections in place—a review never undertaken by the district court—demonstrates why USDA was correct to conclude that there is virtually no risk of contamination of the U.S. cattle beef supply, and therefore no risk to human health from cattle imported from Canada.

First, USDA conducted a thorough investigation of Canadian BSE risk management practices and standards and found that they meet established standards. (AR8316-45.) The two nations are cooperating to ensure compliance with the high standards Canada has put in place.[11] Canada has had an import ban in place for as long as the United States, which helps protect against infection of its cattle supply from foreign sources. 70 Fed. Reg. at 467. Canada has had a feed

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11 *USDA Assessment*, *supra* note 8.

ban in place for seven years, which helps cut off the most common source of transmission of BSE in cattle.[12] *Id.* at 467-68. With an incidence rate of only 0.36 per million[13] over the past two years, USDA rightly concluded that Canada's risk management systems make it currently highly unlikely that Canadian cattle would be exposed to BSE, and virtually impossible that Canadian cattle born today would be exposed to BSE at dangerously high levels. Indeed, Canada's controls are so effective that USDA has also rightly concluded that beef from Canadian cattle is safe for human consumption. Based on the detailed and scientifically sound review of Canada's BSE risk management practices in the record and discussed above, USDA presently allows the import, under permit, of certain Canadian beef products for sale to consumers.[14]

Second, building from that sound premise, USDA further considered the best scientific evidence regarding the growth of BSE prions in an animal's system, and adopted additional precautions to reduce the risk of BSE infection in

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[12] The scientific evidence strongly indicates that BSE is transmitted most effectively when an animal receives in its feed a portion of certain animal parts—most notably the brain and spinal cord—known to carry the BSE agent; elimination of these parts from animal feed can have a dramatic impact on the spread of BSE within a nation's cattle population. 70 Fed. Reg. at 462 (describing dramatic decrease in number of confirmed cases of BSE in UK following implementation of its feed ban).

[13] The district court erred when it concluded that the incidence rate in Canada was 5.5 per million. *See infra* at 22-23.

[14] Animal & Plant Health Inspection Serv., U.S. Dep't of Agric., Questions and Answers, at http://www.aphis.usda.gov/lpa/issues/bse/QA_bserule10-03.pdf (last

the United States. The agency chose to restrict the importation of cattle for slaughter to cattle that are younger than 30 months of age. 70 Fed. Reg. at 483. This decision was based on "a sound and compelling scientific basis for more focused regulatory restrictions with regard to BSE than those we have been operating under." *Id.* at 463. Because the likelihood that such cattle will be exposed to a high concentration of BSE prions in Canada is low, this limit provides an additional layer of protection. The slaughter of a 30-month-old animal poses an even further reduced risk of carrying BSE prions at a level that would pose a danger to either animal or human health.

Third, USDA noted that the practice of SRM removal[15] alone, even in the absence of other protective measures, reduces potential human infection by 95%. *Id.* at 467; (AR1882). The district court did not challenge this finding, but instead noted that "it is no longer reasonable to presume that there is *no* risk of exposure to BSE *infectious agents* once an SRM removal requirement is in place." (Order at 15.) This sentence alone well captures the fundamental error in the decision below. Neither the law, nor common sense, requires adoption of regulations ensuring that there is "*no* risk of exposure to BSE infectious agents." No such standard ever could be achieved, absent the elimination of beef from the

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visited April 19, 2005).

[15] SRM removal refers to the removal of neurological and other parts of a slaughtered animal. 70 Fed. Reg. at 466.

U.S. diet. Instead, the USDA applied reasonable and scientific analysis to determine that the final rule poses virtually no risk of contamination of the U.S. cattle beef supply, and therefore no risk to human health.

In sum, given the risk management system in place between and within Canada and the United States, there is no basis for barring the importation of Canadian cattle under 30 months of age for slaughter. R-CALF has no meaningful likelihood of success on the merits of its challenge.

In addition to the flaws in its overall approach to the health issues in this case, the district court clearly erred with regard to a number of important factual findings.

Unable to point to any actual case where a human consumer was infected by beef from any North American BSE-infected cattle, the district court offers a broadside attack on the food safety measures in place in Canada. The Court criticizes the adequacy of Canadian testing (Order at 10), characterizes the rate of BSE infection in Canada as 5.5 per million head, a rate "on par with a number of European countries with a BSE problem" (*id.* at 11), and concluded that the Canadian feed ban is insufficient because it has been in place only 7 years (*id.* at 13-14). Each of these points individually was considered and rejected, with explanation, by the agency.

At the outset, the correct incidence rate in Canada is quite simple to calculate from the evidence in the record. Pursuant to OIE standards (calculating 4 incidences of BSE over an estimated 5.5 million head of cattle in Canada and annualizing the number because the four incidences took place over the past two years, 70 Fed. Reg. at 464), the calculation is: 4/5.5/2=0.36 cases per million per year over the past two years.[16] Even apart from the obvious methodological flaws of R-CALF's expert, the district court had an obligation to attempt to explain why it would credit R-CALF's expert over USDA's reliance on the OIE expertly determined and standardized process. *See Greenpeace Action v. Franklin*, 14 F.3d 1324, 1332 (9th Cir. 1992) (district court should defer to agency's reliance on its own experts). It did not.

The district court's attack on the Canadian feed ban similarly misses the mark. While the District Court emphasized that the USDA found that Canada's 7-year feed ban was effective despite the fact that OIE generally calls for

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[16] The low incidence rate helps explain, in part, why USDA determined that there was no need to modify its conclusions in light of the late discovery, in December 2004, of the fourth infected cow from Canada. Contrary to the district court's suggestion, the agency is not unwilling to modify its conclusions in light of new facts (Order at 11), but rather the agency, having now fully investigated the risk management procedures in place, no longer views each particular incidence of infection as cause for the same degree of alarm as in May 2003, before the investigation took place. *See* Animal & Plant Health Inspection Service, U.S. Dep't of Argic., Statement at http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2005/02/0047.xml (last visited April, 19 2005).

an 8-year ban (Order at 12-13), that decision was well-founded and based on the evidence. As the USDA explained:

> [W]e stated that, although Canada has had a feed ban in place for only 7 years (1 year less than provided for by OIE), this time period may be conservative because of the variability in the incubation period for BSE. Based on an analysis of data collected in the United Kingdom, the Harvard-Tuskegee Study estimates that the variability distribution for the BSE incubation period in cattle has a median (50th percentile) of approximately 4 years and a 95th percentile of approximately 7 years.... We determined that the duration of the feed ban in Canada adequately addresses the expected BSE incubation period, taking into consideration all of the actions Canada has taken to prevent the introduction and control the spread of BSE (*e.g.*, import controls, level and quality of surveillance, effectiveness of feed ban, epidemiological investigation of detected cases, and depopulation of herds possibly exposed to suspected feed sources). We, therefore, concluded that a feed ban of less than 8 years' duration was appropriate for Canada.

70 Fed. Reg. at 470 (citation omitted). This careful analysis of Canada's feed ban, in conjunction with its overall BSE risk management systems is precisely what OIE encourages when evaluating a nation's feed ban. The eight year limit was never intended by OIE to be a rigid time period, but was understood to be a guideline that had to be evaluated in light of precisely the kind of analysis that APHIS undertook. (ER105-07.) The decision below simply does not address the agency's reasoning or conclusions. In light of these errors, the preliminary injunction order should be reversed.

B. The District Court Erroneously Treated The Prudent Adoption Of An Emergency Rule As A Longstanding Policy And Erroneously Placed A Heavy Burden On The Agency To Justify Altering The Emergency Rule.

The district court fundamentally misperceived the history and nature of the final rule under review. From the outset, the district court characterized the final rule as a regulation that "reversed a May 29, 2003, APHIS decision banning imports of cattle and edible bovine products from Canada." (Order at 1-2.) In so characterizing the issues, the district court proceeded as though the May 29, 2003 rule reflected a considered policy judgment meriting the same level of respect as the final rule itself. Put simply, the district court placed a burden on APHIS to justify its Final Rule as a change in policy from the emergency rule.[17]

As the Supreme Court made clear in *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), any "presumption" in favor of the status quo applies only to changes in "settled" policy. That is because "[a] '*settled course of behavior* embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress.'" *Id.* at 41-42, quoting *Atchison, Topeka & Santa Fe Ry. v. Wichita Bd. of Trade*, 412 U.S. 800, 807-08 (1973), (emphasis added); *see*

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[17] As noted above, the final rule is amply supported by the facts even under the district court's erroneous presumption in favor of the interim rule.

also Chen v. Carroll, 866 F. Supp. 283, 287 (E.D. Va. 1994) ("The *State Farm* holding applies to 'settled' rules.").

The May 29, 2003 emergency rule that temporarily barred import of Canadian beef cattle was not such a "settled" policy. The May 29, 2003 rule was an "interim rule," adopted quickly ("on an emergency basis") in response to the May 20, 2003 discovery of a cow imported from Canada infected with BSE. 68 Fed. Reg. 31939, 31939-40. Having been adopted 9 days after the discovery of the infected cow, there was no time for public comment or much analysis. *Id.* at 31940. As an exercise in caution, the agency stopped importation of Canadian cattle and beef products until it had a chance to study the matter further. *Id.* The question the agency confronted in May 2003 was: Is Canadian beef, which has always been considered safe, still safe? To answer the question, APHIS undertook a nearly two-year long process of investigation and public comment leading up to the final rule on the importation of Canadian cattle and beef products.[18]

Thus the "change" made by the final rule was simply the *restoration* of the long-standing policy to *permit* importation of Canadian cattle. *State Farm* should not have been applied to create a presumption in favor of the emergency

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[18] The agency published an initial proposed rule in November 2003, 68 Fed. Reg. 62386 (Nov. 4, 2003), an interim final rule in January 2004, 69 Fed. Reg. 1862 (Jan. 12, 2004), reopened the comment period on the proposed rule in March 2004, 69 Fed. Reg. 10633 (Mar. 8, 2004), and adopted the Final Rule under review in January 2005, 70 Fed. Reg. 460 (Jan. 4, 2005).

rule, and against the final rule. Such a temporary, emergency measure is simply not entitled to any presumption in favor of its permanence. *See, e.g.*, *Zhang v. Slattery*, 55 F.3d 732, 747 (2d Cir. 1995) (holding that an interim rule could not be considered "settled"); *Competitive Telecomm. Ass'n v. FCC*, 117 F.3d 1068, 1075 (8th Cir. 1997) (noting that agencies may properly devote fewer resources to refining an interim rule).

Agencies often adopt interim rules (rules that take effect before an opportunity for public comment) in circumstances like the present case: where "some exigency ... provides good cause for dispensing with public participation." Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 Admin. L. Rev. 703, 710 (1999). An interim rule "is effective immediately, but it also serves as a notice of proposed rulemaking for the final rule that will supplant it." *Id.* at 704. The May 2003 rule was, from its inception, like many other interim rules, adopted with a view to its eventual displacement by a final rule.

Although federal agencies often are not *required* by law to follow ordinary notice and comment procedures and produce a final rule that displaces the interim final rule, agencies often voluntarily undertake that burden because they "wish to adopt rules that are as effective, efficient, and widely accepted as possible." *Id.* at 711. Even in the ordinary, non-emergency rulemaking process, "administrative authorities must be permitted ... to adapt their rules and policies to

the demands of changing circumstances." *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968). It simply makes no sense to impose an additional burden of justifications on an agency when it adopts a final regulation after notice and comment rulemaking to replace an emergency rule.

Animal health and safety are enhanced when APHIS has the flexibility to respond to unforeseen events—like the discovery of the infected cow in May 2003—with swift action that does not pre-judge the agency's thorough investigation and analysis. But a legal presumption binding APHIS to its initial response would discourage APHIS (and other agencies) from reacting quickly. If the adoption of an emergency rule narrows an agency's discretion to adopt the best policies in the long run, many regulators may choose to run a short-term risk in order to ensure adoption of the best long-term policy.

In this case, the district court's erroneous application of a *State Farm* presumption threatens to upset the delicate balance between strong emergency action and deliberate, well considered long-term policymaking. The preliminary injunction should thus be reversed.

II. THE PUBLIC INTEREST FAVORS IMPLEMENTATION OF THE FINAL RULE.

"The district court must ... consider whether the public interest favors issuance of the injunction." *Shelley*, 344 F.3d at 917. In granting the preliminary injunction, the district court determined that the public interest favored halting

implementation of the final rule entirely because it erroneously believed the final rule would undermine the safety of the meat supply in the U.S., and pose a risk to consumers, as well as raise the possibility of stigmatizing U.S. meat products around the world. (Order at 26.) None of these findings is supported by the record.

The decision below actually undermines the public interest by ignoring a particularly detailed and well reasoned regulatory analysis in favor of the views of a small group of self-interested cattlemen who are concerned only with prohibiting the import of cattle with which they would otherwise have to compete.

Other cattlemen's groups have taken a more thoughtful, even-handed view. As the National Cattlemen's Beef Association ("NCBA") has said: "litigation based on unfounded science threatens beef demand" because it undermines confidence in the safety of the meat supply in the country.[19] In addition, the NCBA has recognized that U.S. cattlemen and meat packers who wish to export American beef know that their potential overseas customers, and their governments, are "watching to see whether the U.S., when dealing with Canada, will make its own decisions based upon sound science. Simply put, if we

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[19] Jim McAdams, Nat'l Cattlemen's Beef Assoc., NCBA Statement (Mar. 17, 2005), at http://www.beefusa.org/NEWSNCBAStatementUSDADecisiontoAppealUSDistric

don't agree that beef from Canadian cattle under 30 months of age is safe — then what assurances can we offer the world that our beef is safe ...."[20]

Applying sound scientific analysis in this case is important to the United States's effort to influence the views of our trading partners, especially Japan, to adopt science-based standards recognizing that U.S. beef is safe.[21] It is in the United States's interest for our trading partners to adopt the same kind of rigorous, scientific approach to the risk of BSE transmission in beef that is reflected in the final rule. Given the degree of scientific understanding and risk assessment already achieved, isolated incidents should no longer trigger emergency responses. If the best available systems of control are in place, the public—the U.S. public, Japanese public, Canadian public, and the world—can remain confident that the beef supply is safe. On the other hand, R-CALF's

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tCourtInjunctionofBSEMinimal-RiskRule21283.aspx (last visited April 19, 2005).

[20] Nat'l Cattlemen's Beef Assoc., *It Is Time to Reopen the Canadian Border* (2005), at http://www.beefusa.org/newsitistimetoreopenthecanadianborder3512.aspx (last visited April, 19, 2005).

[21] James Brooke, *Japan Still Bans U.S. Beef, Chafing American Officials*, New York Times, April 21, 2005, at http://www.nytimes.com/2005/04/21/business/worldbusiness/21beef.html? (noting that Japan continues to block imports of American cattle despite having confirmed several more BSE infected cows within its borders) (last visited April 21,2005); Mari Yamaguchi, *Japan Says: 'Where's the (U.S.) Beef?'*, Grand Forks Herald, Mar. 31, 2005, at http://www.grandforks.com/mld/grandforks/business/11272176.htm (stating that Japan's ban of beef imports from the U.S. "has caused discord between the two countries" raising the threat of sanctions from some U.S. lawmakers) (last visited

approach, as adopted by the district court, simply promotes irrational fear and deprives the public of regulation grounded in sound science.

CONCLUSION

For the foregoing reasons, this Court should reverse the preliminary injunction order and permit the final rule to take effect.

Respectfully submitted,

Carter G. Phillips
Alan Charles Raul
Mark D. Hopson
Jay T. Jorgensen
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Robert N. Hochman
Chad W. Pekron
SIDLEY AUSTIN BROWN & WOOD LLP
Bank One Plaza
10 South Dearborn Street
Chicago, IL 60603
(312) 853-7000

April 19, 2005).

CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)(B) AND NINTH CIRCUIT RULE 32-1

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and Ninth Circuit Rule 32-1, I certify that the attached Replacement Brief of Amicus Curiae In Support of Appellants uses a proportional font and, according to the word count function of the word processing program used to create the brief (Microsoft Word), has 6,441 words.

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Robert N. Hochman

CERTIFICATE OF SERVICE

I hereby certify that pursuant to Fed. R. App. P. 25(d)(2) and 31(b) on April 26, 2005, I caused two copies of the foregoing brief to be served by Federal Express overnight delivery on the following:

A. Clifford Edwards
Edwards, Frickle, Anne-Hughes,
Cook & Culver
1601 Lewis Avenue, Suite 206
Billings, MT 59104

Russell S. Frye
Frye Law PLLC
3050 K Street, NW
Suite 400
Washington, D.C. 20007-5108

William L. Miller
The William Miller Group, PLLC
3050 K Street, NW, Fourth Floor
Washington, D.C. 20007

Philip C. Olsson
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, NW
Washington, D.C. 20036-2220

Mark B. Stern
Michael S. Raab
Civil Division, Room 7256
Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530-0001

I also hereby certify, pursuant to Fed. R. App. P. 25(d)(2), that on April 26, 2005 I filed an original and 15 copies of the foregoing brief by causing them to be sent by Federal Express overnight delivery to:

Ms. Cathy Catterson
Clerk, United States Court of Appeals for the Ninth Circuit
95 Seventh Street
San Francisco, CA 94103-1526

_____
Robert N. Hochman